REMARKS/ARGUMENTS

The Invention

The invention is directed to an isolated or purified human nucleic acid comprising the nucleotide sequence of SEQ ID NO: 1.

The Pending Claims

Claims 3 and 16-18 currently are pending.

The Amendments to the Claims

The claims have been amended to claim more distinctly and point out more particularly the present invention. Specifically, claim 1 has been amended to recite a human nucleic acid sequence comprising the nucleotide sequence of SEQ ID NO: 1. This amendment is supported by the specification at, e.g., page 8, last paragraph. Claims 12-15 have been cancelled. Accordingly, no new matter has been added by way of these amendments.

The Office Action

The Office Action raises the following concerns:

(a) an English translation of the German priority application must be provided in order to obtain the benefit of foreign priority under 35 U.S.C. §§ 119(a)-(d),

(b) claims 12, 13, 14, and 15 are objected to because the claims encompass nonelected subject matter,

(c) claims 3 and 12-18 are rejected under 35 U.S.C. §§ 101 and 112, first paragraph, because the claimed invention allegedly is not supported by either a specific and substantial asserted utility or a well-established utility,

(d) claims 3 and 12-18 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description and enablement requirements,

(e) claims 3 and 12-18 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Santoro et al., *Proc. Natl. Acad. Sci. USA*, *94*: 14815-14820 (1997) ("the Santoro reference"),

(f) claims 3 and 16-18 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent 5,849,870 (Warren et al.) ("the Warren patent"), and

(g) claims 3 and 12-18 are rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent 6,703,485 (Kandel et al.) ("the Kandel patent").

Reconsideration of these rejections is respectfully requested.

Discussion of Foreign Priority

The Office Action indicates that an English translation of the German priority application must be provided in order to obtain the benefit of foreign priority under 35 U.S.C. §§ 119(a)-(d). Applicants submit herewith such a translation. The priority date of the subject application is February 17, 1998 (i.e., the filing date of the German priority application).

Discussion of Claim Objection

Claims 12-15 have been objected to for being drawn to nonelected subject matter (i.e., SEQ ID NOs: 2, 3, 4, 5, and 12). Claims 12-15 have been cancelled, thereby rendering the objection moot.

Discussion of Rejection Under 35 U.S.C. §§ 101 and 112, First Paragraph

The Patent Office has rejected claims 3 and 12-18 under Section 101 as allegedly lacking a specific and substantial utility or a well-established utility, and under Section 112, first paragraph, for insufficiency of disclosure. These rejections are traversed for the reasons set forth below.

Applicants have indicated that the claimed nucleic acid sequences can be used in a screening or diagnostic method (see specification at, for example, page 1, second paragraph.). As indicated at, for example, page 8, fifth paragraph, through page 9, line 8, of the specification, the claimed nucleic acid sequences can be used to test the effect of substances on ion channels. Applicants have also indicated that the claimed nucleic acid sequences can be used for the treatment and/or prophylaxis of cardiovascular disorders, sleep disturbances, disturbances of consciousness, and pain (see specification at, for example, pg. 1, third paragraph, and page 13, third paragraph). As indicated at, for example, page 13, third paragraph, of the specification, the claimed nucleic acid sequences can be used to treat or recognize at an early stage a cardiovascular disorder due to faulty control of the sinus node, to recognize disturbances of consciousness due to malfunctioning corticothalamic neurons, and as gene therapy of a patient in which the channel is no longer operative.

Evidence of pharmacological or other biological activity of a compound is relevant to an asserted therapeutic use if there is a *reasonable* correlation between the activity in question and the asserted utility. *Cross v. Iizuka*, 753 F.2d. 1040, 224 U.S.P.Q. 739 (Fed. Cir. 1985); *In re Jolles*, 628 F.2d. 1322, 206 U.S.P.Q 885 (C.C.P.A. 1980); *Nelson v. Bowler*, 626 F.2d. 853, 206 U.S.P.Q. 881 (C.C.P.A. 1980). An applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence (e.g., articles in scientific journals), or any combination thereof. The applicant does not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty, nor does the applicant have to provide actual evidence of success in treating humans where such a utility is asserted. M.P.E.P. § 2107.03.

As discussed above, Applicants have demonstrated that the specification of the subject application discloses a reasonable correlation between the activity of the I_h ion channels and the asserted utility. This reasonable correlation also is evidenced by documentary evidence. In this respect, Bucchi et al., *J. Gen. Physiol.*, *120*: 1-13 (2000) (copy enclosed), discloses the use of I_h ion channels in a pharmacological context, particularly in the regulation of heart rate. In addition, Chaplan et al., *J Neurosci.*, *23*(4), 1169-78 (2003) (copy enclosed) discloses the potential use of ion channels in the treatment of pain, while WO 99/18941 (Dijcks et al.) (copy enclosed) describes the use of I_h ion channel modulators to treat psychiatric disorders including depression. Moreover, both Seifert et al., *Proc. Natl. Acad. Sci. USA*, *96*, 9391-9396 (1999) (copy enclosed), and Ludwig et al., *EMBO J.*, *18*, 2323-2329 (1999) (copy enclosed), confirm that SEQ ID NO: 1 encodes an I_h ion channel.

In view of the foregoing, Applicants submit that the aforementioned utilities are specific, substantial, and credible as prescribed in M.P.E.P. § 2107.01. Accordingly, Applicants request the withdrawal of the rejections under Section 101 and 112, first paragraph.

Discussion of Rejections Under 35 § U.S.C. 112, First Paragraph

Claims 3 and 12-18 have been rejected under Section 112, first paragraph, for an alleged lack of written description and enablement. These rejections are traversed for the reasons set forth below.

Solely in an effort to advance prosecution of the subject application, and not in acquiescence of the rejection, claim 3 has been amended to recite an isolated or purified human nucleic acid comprising the nucleotide sequence of SEQ ID NO: 1. The subject matter of claim 3 is described in the specification at, for example, page 8, last paragraph. Moreover, the specification discloses how to isolate a nucleotide sequence comprising SEQ ID NO: 1 at, for example, the Examples. The specification discloses methods for generating vectors, cells, and compositions comprising a nucleic acid sequence of SEQ ID NO: 1 at, for example, page 10, line 5 - page 12, line 4, and page 14, third paragraph - page 16, first paragraph. Methods for administering a polypeptide encoded by SEQ ID NO: 1 for therapeutic or prophylactic use are disclosed in the specification at, for example, page 12, second paragraph - page 13, fourth paragraph, and page 16, second paragraph - page 17, second paragraph.

In view of the foregoing, Applicants submit that the specification adequately describes and enables the invention defined by claim 3, and claims 16-18 depending therefrom. Accordingly, the written description and enablement rejections under Section 112, first paragraph, should be withdrawn.

Discussion of Rejections Under 35 U.S.C. § 102(b)

Claims 3-18 have been rejected under Section 102(b) as allegedly anticipated by the Santoro reference and by the Warren patent. These rejections are traversed for the reasons set forth below.

The Santoro reference reportedly discloses an isolated cDNA for a cyclic nucleotide-gated channel that is 90% identical to SEQ ID NO: 1 as shown in a sequence alignment provided by the Examiner. The alignment of SEQ ID NO: 1 and the cDNA disclosed in the Santoro reference, however, indicates that there are 10 sequence mismatches. Moreover, SEQ ID NO: 1 is 1792 nucleotides in length, while the cDNA sequence disclosed in the Santoro reference is 1250 nucleotides in length. Thus, the Santoro reference does not disclose or suggest an isolated nucleic acid comprising a nucleotide sequence of SEQ ID NO: 1, as required by the pending claims

The Warren patent allegedly discloses a nucleic acid sequence that comprises at least six nucleotides of SEQ ID NO: 1 for use as an insecticide. The Warren patent, however, does not disclose or suggest a nucleic acid comprising a nucleotide sequence comprising SEQ ID NO: 1, as required by the pending claims.

In view of the foregoing, neither the Santoro reference nor the Warren patent anticipates the subject matter of claim 3, or claims 16-18 depending therefrom. Accordingly, the Section 102(b) rejections should be withdrawn.

Discussion of Rejection under 35 U.S.C. § 102(e)

Claims 3-18 have been rejected under Section 102(e) as allegedly anticipated by the Kandel patent. This rejection is traversed for the reasons set forth below.

A patent qualifies as prior art under Section 102(e) if the patent has an effective filing date prior to the date of invention for the claims in issue. Here, the Kandel patent allegedly has an effective filing date of May 28, 1998. However, the date of invention for the claims in issue is at least as early as February 17, 1998, i.e., before the alleged effective filing date of the Kandel patent, as demonstrated by the text of the German patent application to which the present application claims priority under 35 U.S.C. § 119. An English translation of the German patent application to which the present application claims priority is concurrently filed herewith. As is apparent from the English translation, the German patent application fully supports the pending claims, and it is clear that Applicants invented the subject matter of the pending claims prior to the alleged effective filing date of the Kandel patent. As a result, the Kandel patent is not prior art to the pending claims under 35 U.S.C. § 102(e). See also M.P.E.P. § 2136.05.

Conclusion

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

Respectfully submitted,

Melissa E. Kolom, Reg. No. 51,860
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6780
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

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